4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0043]

Understanding Priorities for the Development of Digital Health Technologies to Support Clinical Trials for Drug Development and Review; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Understanding Priorities for the Development of Digital Health Technologies To Support Clinical Trials for Drug Development and Review." Convened by the Duke-Robert J. Margolis, MD Center for Health Policy and supported by a cooperative agreement between FDA and Duke-Margolis, the purpose of the public workshop is to understand the priorities for the development of Digital Health Technologies (DHTs) to support clinical drug trials, including accessibility, diversity, and clinical outcome measures using DHTs. Additionally, this public workshop meets a Prescription Drug User Fee Amendments (PDUFA VII) commitment to convene the first of a series of public workshops by the end of the second quarter (Q2), fiscal year (FY) 2023.

DATES: The public workshop will be held virtually on March 28, 2023, and March 29, 2023, from 1 p.m. to 5 p.m., Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom Platform. The link for the public workshop will be sent to registrants upon registration.

FOR FURTHER INFORMATION CONTACT: Capt. Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301-796-3161, Dianne.Paraoan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII), included as part of the FDA User Fee Reauthorization Act of 2022, highlights the goals of facilitating timely access to safe, effective, and innovative new medicines for patients. The commitments in the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 document (available at: https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027) focus on activities to enhance the use of DHTs to support drug development and review, including working with the Digital Health Center of Excellence.

To meet a PDUFA VII commitment, FDA agreed to convene a series of five public workshops with key stakeholders including patients, biopharmaceutical companies, DHT companies, and academia to gather input into issues related to the use of DHTs in regulatory decision-making. The objective of this first workshop is to understand priorities for the development of DHTs to support clinical drug trials, including the potential for DHTs to increase clinical trial accessibility and diversity, as well as the use of DHTs to capture clinical outcome measures. The public workshop scheduled for March 28 and 29, 2023, fulfills the commitment to convene the first of a series of five public workshops by the end of Q2, FY 2023.

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to discuss with stakeholders priorities and challenges for the development of DHTs to support clinical drug trials, including, but not limited to:

- improving participant access, increasing diversity, and facilitating engagement through remote trial-related measurements;
- understanding patient and industry perspectives;
- understanding opportunities for remote data acquisition directly from trial participants; and

- using DHTs to capture clinical outcomes measures.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://duke.is/pzkwx. Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Registration is free and people interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations, please contact Margolisevents@duke.edu no later than March 7, 2023. Please note, closed captioning will be available automatically.

Dated: February 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-02479 Filed: 2/3/2023 8:45 am; Publication Date: 2/6/2023]